Public Health and the Law

From Health-Based to Technology-Based Standards for Hazardous Air Pollutants

James C. Robinson, PhD, MPH, and William S. Pease, MS

ABSTRACT

The Clean Air Act Amendments of 1990 represent a major shift in regulatory emphasis for toxic air pollutants. Recognizing the immediate public health benefits that can be gained from the application of currently available and affordable control technologies, Congress has abandoned its insistence that health risks should be the only consideration in establishing emissions standards. Previously excluded concerns about economic costs and technological feasibility will now determine the initial level of pollution control required of toxic air pollution sources. In exchange for reducing the stringency of emissions limits, the newly amended act extends the scope of regulation by listing 189 toxic substances that must be controlled over the next decade. This exchange of regulatory depth for breadth occurs against a history of reluctance by the Environmental Protection Agency to implement the original health-protective language of the Clean Air Act. It mirrors earlier compromises under the Clean Water Act and the Occupational Safety and Health Act. (*Am J Public Health.* 1991;81:1518–1523)

The 1990 amendments to the Clean Air Act dramatically change the basic structure of the nation's regulatory approach to toxic air pollutants. Recognizing the regulatory paralysis that has accompanied congressional insistence that emissions standards be based on health considerations alone, the recent amendments give the Environmental Protection Agency (EPA) authority to base standards on available and affordable control technologies. The recent amendments shift EPA's focus from developing a few health-based standards to issuing numerous technology-based standards. Whereas the 1970 act mandated stringent emissions limits and gave EPA complete discretion to select substances for regulation, the 1990 act grants EPA discretion to determine the levels of control required, but mandates that it regulate 189 specified substances.

The striking political feature of these amendments is the virtual unanimity with which the usually fractious participants in air toxics debates agreed to the final compromise. This convergence is a political response to the fundamental weakness of the original statute. In 1970 Congress interpreted the public health problem posed by airborne toxics as one of very high risks from a very small number of substances. Congress therefore wrote a statute that gave EPA great discretion in identifying particular substances as regulatory targets, but virtually no discretion with respect to the stringency with which identified toxics must be controlled.[1] Since 1970, however, the public health problem posed by toxic air pollutants gradually has been reinterpreted as transcending the relatively modest cancer risks posed by the few substances that have been the focus of scientific and regulatory attention.[2] Concern has grown over the cumulative cancer risk due to exposure to low levels of many substances,[3] and over other adverse health effects, such as reproductive and neurological toxicity.[4] This new scientific understanding suggests the need for a regulatory system that covers large numbers of substances with only moderately stringent standards for any one substance.

The exchange of regulatory depth for regulatory breadth that is embodied in the 1990 Amendments came only after two decades of conflict and attempts at compromise. EPA initially responded to the mandate for what it considered unjustifiably strict emissions limits by reinterpreting the 1970 statute as permitting less strict, technology-based limits. It also resisted identifying particular toxic substances as targets for regulation. Environmental organizations were more disturbed by EPA's delays in listing substances than by the technology-based nature of those standards that were imposed. Given that total discretion over listing had been granted EPA in the 1970 statute, however, the environmental organizations had no direct means to pressure the agency to list and regulate more substances. Therefore, they relied on the act's nondiscretionary requirement for health-based emission

The authors are with the School of Public Health of the University of California, Berkeley.

Requests for reprints should be sent to James C. Robinson, PhD, MPH, Center for Occupational and Environmental Health, School of Public Health, University of California, Berkeley, CA 94720.

Editor's Note. George J. Annas, JD, MPH, is the editor of the journal's Public Health and the Law department. Contributions for this department should be addressed to him as follows: George J. Annas, JD, MPH, Chair, Health Law Department, Boston University, Schools of Public Health and Medicine, 80 East Concord Street, Boston, MA 02118.

limits to attack EPA's technology-based standards as insufficiently stringent. They hoped to motivate the agency to negotiate a compromise that saved its technological orientation in exchange for an acceleration of the listing process. The 1990 amendments can be interpreted as the belated success of this environmentalist strategy.

This article analyzes the shift in the basis for standard-setting for hazardous air pollutants under Section 112 of the Clean Air Act. The first section contrasts the new statutory mandate with the old, emphasizing the shift in EPA discretion from identification of regulatory targets to decisions over how stringently to control each of a large number of substances. The second and third sections describe the two major cycles of conflict and attempted compromise as EPA, environmental organizations, and polluting industries groped toward an exchange of regulatory depth for regulatory breadth. The final section evaluates the public health significance of the transition to technology-based emissions limits for hazardous air pollutants.

The 1970 Act and the 1990 Amendments

Section 112 of the Clean Air Act of 1970 had a simple two-step structure for controlling hazardous air pollutants, defined as substances "which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness."[5] First, EPA was required to publish a list of pollutants for which it intended to establish an emission standard. Second, within 360 days of listing a substance, EPA was required to establish an emissions standard that "provides an ample margin of safety to protect the public health." Section 112 established no mandate for EPA to consider the economic costs or technological feasibility of its health-based emissions standards. Once EPA listed a substance as a hazardous air pollutant, an emissions standard was to be based only on health considerations. EPA, however, retained total discretion as to whether to list a particular substance in the first place.[6]

Under the amendments of 1990,[7] Section 112 also has a simple two-step structure, but now the locus of EPA's discretion is the reverse of that in the previous version. The text of the amended statute contains a list of 189 substances that EPA must consider as hazardous air pollutants, including 9 that EPA had previously evaluated and declined to regulate. Any person may petition EPA to add a substance to the list, and the agency is given 18 months to either list the substance or present reasons for not listing it.

The amendments grant EPA considerable latitude to decide on the stringency of the emissions standards it promulgates. These standards shall require the maximum degree of reduction in emissions that EPA determines is "achievable" after "taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impact and energy requirements."[8] The standards shall incorporate the "maximum achievable control technology" (MACT), a stringent version of the technology-based approach adopted for "criteria" air pollutants under other sections of the Clean Air Act,[9] and for toxic water pollutants under the Clean Water Act.[10] The amendments provide the agency considerable latitude in establishing categories of emissions sources and in designating a particular emission level as achievable for each category after taking into consideration the costs of compliance. In principle, the standards are to reduce the emissions of all existing sources in a category to a level no greater than the levels achieved by the "best performing" 12% of existing sources in that category. Standards for newly constructed or extensively modified industrial plants can be more stringent. Standards are to be promulgated for 40 source categories by 1992, for 25% of all categories by 1994, for an additional 25% by 1997, and for all categories by 2000. Emissions standards are to be reviewed and revised at least every 7 years.

The health-based approach embodied in the original Clean Air Act of 1970 has not been totally abandoned, but its implementation has been postponed years into the future. Initial application of MACT will reduce the public health risks from many sources of air toxics, but significant residual risks may remain. Congress considered several new approaches to managing these risks, including emissions taxes to stimulate continuing pollution reduction[11] and explicit risk-based standards to identify when further controls are necessary.[12] It ultimately settled, however, on a version of the "ample margin of safety" approach from the original Section 112.[13] Control beyond MACT will generally be required to reduce risks from sources posing cancer risks above 1 in 10 000 for the most-exposed individuals and 1 in 1 000 000 for the majority of the exposed population. The first set of residual risk-based standards are to be promulgated by 2001.

Conflict and Compromise: Round 1

The first round of conflict, compromise, and renewed conflict began soon after the passage of the 1970 act, as EPA began to search for ways to avoid implementing the literal language of Section 112. EPA listed asbestos, mercury, and beryllium promptly in 1971, but then missed the statutory deadlines for promulgating emissions standards that would provide "an ample margin of safety." The agency developed an elaborate mechanism for delaying regulatory action, principally through ever more comprehensive evaluations of the health risks posed by individual substances.[14] It was evident that some toxic substances had no apparent threshold of safety, and hence that EPA's compliance with the "ample margin of safety" language of Section 112 would require that these substances be banned. In its original proposed regulation for asbestos, the first carcinogen treated under Section 112, EPA was forthright in declaring that no threshold of safety was known, and discussed the possibility of a ban on the substance.[15] This option was rejected on the grounds that it would have drastic economic consequences. The final standard for asbestos declares that only health factors were considered, but then contradicts itself by stating that a ban on the substance was not justified because of the effects on the economy.[16] No environmental group contested EPA's refusal to implement the health-at-any-cost language of Section 112 in the asbestos standard.

By 1975, when EPA proposed emissions standards for vinyl chloride, it explicitly acknowledged the prominent role played by technological and economic factors in its implementation of Section 112.[17] It emphasized the scientific consensus that no margin of safety existed for exposure to carcinogens and that there existed no technological means for using vinyl chloride with zero emissions into the atmosphere. A literal interpretation of Section 112 would therefore require a ban on the substance, something which EPA argued Congress could not have intended. EPA claimed that a "best available control technology approach will produce the

most stringent regulation of hazardous air pollutants short of requiring a complete prohibition in most instances." A technology was defined as "available" if it was in use in one or more plants and if it did not impose costs that were "grossly disproportionate" to the benefits from the emissions reduction achieved.

The proposed vinyl chloride standard received two widely diverging sets of comments. The regulated industries argued that EPA should set standards based on formal cost-benefit analysis and should conduct such an analysis for each smokestack and valve subject to regulation. The Environmental Defense Fund (EDF) claimed that Section 112 required a ban on the uses of vinyl chloride for which substitutes existed, as well as stringent emission controls on the uses for which there were no substitutes. Significantly, the EDF did not call for a literal implementation of the language of the statute; instead, it emphasized a "technology-forcing" interpretation of Section 112.[18] When EPA promulgated a final vinyl chloride standard similar to the initial proposal,[19] the EDF took its case to court.[20]

In February 1977, EPA accepted most of the positions advanced by the EDF and settled the case out of court. An official proposal to revise the vinyl chloride standard followed several months later.[21] The proposal embraced the goal of zero emissions through the forcing of technological innovation. The "grossly disproportionate" language was gone and the tone of the proposal seemed to reflect a greater willingness to impose substantial costs on the affected industries.

The proposed revisions to the vinyl chloride standard were placed in abeyance until EPA developed a generic policy for the identification and regulation of airborne carcinogens. This shift from a substance-by-substance focus to a generic approach followed the pattern of a settlement EPA had reached with environmental groups over the regulation of toxic water pollutants. Similarly to Section 112 of the Clean Air Act, Section 307 of the Federal Water Pollution Control Act of 1972 required EPA to formulate a list of toxic water pollutants and establish, within 1 year, effluent limits that provided an "ample margin of safety."[22] Concerned about the economic impact of such stringent effluent limits, EPA delayed the implementation of this legislative mandate and was brought to court by environmental groups. In a consent decree settlement,[23] a compromise was achieved in which stringency of effluent limits was exchanged for breadth of substances covered. Health-based limits were replaced by economically achievable technology-based standards. EPA agreed to promulgate regulations to control 65 classes of toxic water pollutants from 21 industrial categories according to a prescribed schedule.[24] Congress codified this compromise in the 1977 amendments to what was renamed the Clean Water Act.[25]

EPA's airborne carcinogen policy, proposed in 1979,[26] formalized the exchange of regulatory stringency in favor of regulatory breadth. EPA promised to list as hazardous air pollutants all substances judged to pose a "significant risk" to the population. The significance of the risk would be evaluated in terms of whether the substance in question had a high probability of producing cancer in humans and whether there existed substantial public exposure via the ambient air. This classification scheme was expected to dramatically accelerate the pace of listing under Section 112.

Once a substance was listed as a carcinogen, EPA's attention would shift from health-related factors to technology- and cost-related factors. It did not make sense to forgo the public health benefits that could be gained by applying available control technologies in order to promulgate stringent health-based standards that could not be implemented. Just as in EPA's program for regulating criteria air pollutants such as ozone, the agency would identify alternative control technologies by surveying those currently in use. In a nod to the Clean Air Act's original technology-forcing philosophy,[27] EPA would also examine the applicability of technologies that were not currently in use in the industries in question but which had been demonstrated in pilot tests or other industrial applications. EPA would then select the "best available technology" from the range of identified options. Health factors reentered the regulatory schema in the form of a quantitative risk assessment of the hazard remaining after the "best available technology" had been imposed. If the residual risk was "unreasonable," more stringent controls, possibly including phased reductions in permissible emissions, would be imposed. The determination of "unreasonable" risk would include an evaluation of the economic impacts of imposing controls more stringent than the "best available."

Although it solved EPA's political problems with the environmentalists, the 1979 carcinogen policy contained two structural weaknesses that proved its undoing. First, as a declaration of agency policy rather than a statutory amendment, it left intact EPA's ultimate discretion with respect to identifying, listing, and regulating particular substances. After the appointment of Anne Gorsuch as EPA administrator in 1981, the agency simply ignored the agreement, listing no new substances under Section 112 and promulgating no standards for previously listed substances. Second, the 1979 policy was fatally weakened by the strained interpretation of Section 112 it required in order to justify its "best available technology" approach to setting emission limits. The literal language of Section 112, the internal structure of the Clean Air Act, and the act's legislative history combined to render EPA's interpretation intellectually implausible and politically vulnerable.[28,29]

Conflict and Compromise: Round 2

The inauguration of President Ronald Reagan prompted a return to a strategy of regulatory delay. EPA administrator William Ruckelshaus admitted in congressional oversight hearings that endless evaluation was the agency's response to the inflexible requirements of Section 112: "Where the mandates are unclear or appear to suggest unfeasible programs, they tend to slow down, to 'study the problem,' as the saying goes."[30] Studies could take years. The analysis of vinylidene chloride, for example, began in 1979 and ended in 1985 with an agency decision not to regulate the substance. Ruckelshaus responded to congressional impatience by promising to make listing decisions on almost 30 chemicals by the end of fiscal year 1986.[31] The Agency ultimately placed the substances judged worthy of regulatory attention into a novel "intent to list" category, thereby avoiding Section 112's stringent timeline for promulgating emissions standards.

During the Reagan administration, EPA's air toxics policy was substantially revised. In response to evolving scientific understanding of the problem and a commitment to deregulation, federal control of air toxics through Section 112 was deemphasized.[32] EPA argued that industry accounted for less than 25% of cancer incidence from exposure to air toxics and that state regulation of vehicle emissions and heating sources would provide more effective control of the overall problem. As part of its new policy, EPA formally withdrew the long-dormant 1977 proposal

to amend and tighten the emissions standard for vinyl chloride.[33] After EPA reneged on its promise to accelerate listing, the environmentalists refused to accept "best available technology" in lieu of a genuine "ample margin of safety." The Natural Resources Defense Council (NRDC) decided to challenge the withdrawal of the vinyl chloride revisions on the grounds that it constituted an improper abandonment of the health-only focus of Section 112.[34]

A panel of judges from the US Circuit Court of Appeals for the District of Columbia initially upheld EPA's withdrawal of the vinyl chloride revisions and its "best available technology" interpretation of Section 112.[35] The panel concluded that the silence of Section 112 on the role of technological and economic factors, plus the "ample margin of safety" language, gave EPA discretion to consider nonhealth factors in setting emissions limits.

The full circuit court, sitting en banc, overturned the panel's decision, vacating EPA's withdrawal of the vinyl chloride revisions and invalidating its "best available technology" interpretation of Section 112.[36] The full court's decision acknowledged that Section 112 grants EPA discretion to consider nonhealth factors, but held that the particular manner in which the agency considered those factors in the vinyl chloride standard was unreasonable. It suggested an alternative approach, according to which EPA would first determine a "safe" level of emissions, based exclusively on health factors, and then determine an "ample margin of safetv" below this level, based on a consideration of technological and economic factors. Here, "safe" was defined to permit risks "acceptable in the world in which we live." In effect, the court's interpretation of Section 112 mandated a two-step approach to regulating airborne carcinogens that was the reverse of the two-step approach developed by EPA. Under the "best available technology" approach, nonhealth factors were emphasized in the first step and health factors were emphasized in the evaluation of residual risk. Under the vinyl chloride decision, however, health factors were to be emphasized in the first step and economic factors in the second.

Although it was nominally a victory for the NRDC, the vinyl chloride decision was considered unsatisfactory by all participants in the debate. From the environmentalists' point of view, it did nothing to accelerate the listing of new substances as hazardous air pollutants under Section 112. From EPA's point of view, it gave no guidance as to how economic factors should be handled, since it assumed that the social acceptability of a risk could be evaluated without reference to the economic benefits of the substance that produced the risks. In a policy determination accompanying the first emission standard promulgated after the vinyl chloride decision, covering benzene emissions, EPA attempted to provide a workable definition of "safety." Its standards would generally ensure that maximally exposed individuals would not face an increased lifetime cancer risk of greater than 1 in 10 000, whereas most of the exposed population would not face an increased lifetime cancer risk of greater than 1 in 1 000 000.[37]

Soon after the adverse judicial ruling in 1987, EPA decided to support statutory amendment of Section 112. EPA promoted a policy that resembled the informal compromise of 1979: increased agency discretion over the stringency of emissions standards in exchange for reduced agency discretion over the selection of substances for regulation. The political climate of the late 1980s was different in important ways from the climate earlier in the decade. Regulatory delay was now politically risky. The methyl isocyanate disaster in Bhopal, India, and the subsequent methyl isocyanate leak in Institute, WV, had heightened public and congressional concern for chemical safety.[38] Partly in response to the Bhopal and Institute events, Congress passed the Emergency Planning and Community Right to Know Act in 1986.[39] Among other provisions, this act requires major industrial sources to report annually to EPA the quantity of hazardous substances they emit into the atmosphere. The first reports indicated that 2.7 billion pounds of toxic chemicals were emitted in 1987.[40] EPA identified 205 facilities whose emissions posed cancer risks exceeding 1 in 1000 to individuals in surrounding communities.[41] The political environment at the end of the 1980s resembled that immediately prior to the passage of the Clean Air Act of 1970. A Republican president competed with congressional Democrats for the mantle of protector of the environment; aggressive control of air pollution was the test case. The administration, industry, and the major environmental organizations put their support behind a compromise on Section 112 in which mandatory listing of substances was accepted in exchange for a technology-based approach to establishing emission limits.[42]

Making the Most of MACT

The Clean Air Amendments of 1990 formalize the transition from health-based to technology-based standard-setting for hazardous air pollutants. After years of virulent debate and litigation, the final changes to Section 112 generated remarkably little controversy. Each of the major political actors seems to view the outcome as a net gain. The environmental organizations have achieved a statutorily based guarantee of accelerated listing in exchange for a relatively modest retreat from the health-at-any-cost symbolism of the original Section 112 to the make-your-best-effort symbolism of MACT. The regulated industries have been able to shift the focus of subsequent debate from one that put them at a clear political disadvantage (whether to protect health) to one that gives them a clear technical advantage (the subject of debate is the arcane question of what MACT means for specific substances in specific industrial sectors). EPA escaped the task of implementing unrealistic legislative mandates and can now settle down to the tedious and politically safe business of defining emission categories and available control technologies.

Statutes based only on health risks have imposed significant economic and political costs on the regulatory system. Statutory bans on the consideration of technological and economic feasibility have generated systematic bureaucratic delay under the Clean Water Act and the Occupational Safety and Health Act, as well as under the Clean Air Act. Administrative delay reflects a dynamic in which fear of overregulation leads to underregulation.[28,43] This was evident in EPA's enforcement of the toxic substances provisions of the Clean Water Act prior to the 1977 amendments, which permitted a technology-based approach. EPA had previously managed to establish effluent limits providing an "ample margin of safety" for only six pollutants.[24] The tendency toward underregulation was also apparent in the Occupational Safety and Health Administration's (OSHA) meager record of rule making prior to the promulgation of the 1989 Air Contaminants Standard[44]: OSHA had previously managed to establish health-based exposure limits for only 26 substances.

The "maximum achievable control technology" approach could lead to either overregulation or underregulation. The

essence of MACT is the imposition of emission controls based on technological availability and the industry's financial viability, without regard for whether these controls have a cost-effective impact on prevalent health risks. This raises the specter of overregulation, a situation in which high expenditures are required to reduce trivial risks. High costs per cancer case avoided have been predicted for technology-based standards covering benzene, coke oven emissions, acrylonitrile, radionuclides, and inorganic arsenic.[45,46]

Technology-based regulation also raises the specter of underregulation, since cost, rather than health or environmental risks, determines the levels of control imposed. Perhaps the best example of the potential for underregulation using technology-based standards is the OSHA Air Contaminants Standard, which adopted the threshold limit values of the American Conference of Governmental Industrial Hygienists. Threshold limit values have been shown to represent the exposure levels prevalent in leading firms at the time they are promulgated, rather than "thresholds" of safety,[47–49] and hence embody a mild form of technology-based standards.[50] Similarly, application of technology-based limits for toxic water pollutants has not always resulted in improved water quality.[51–53] Acknowledging the failure of technology-based standards as the sole basis for water pollution policy, Congress amended the Clean Water Act in 1987 to require controls beyond "best available technology" if necessary to protect aquatic life and human health.[54,55]

All parties to the air toxics debate stand to benefit from the Clean Air Act Amendments of 1990. Experience under occupational health and water pollution policy indicates, however, that only the coordinated use of both technology-based and health-based standards promises significant long-term improvements in environmental quality and public health. The Clean Air Act Amendments of 1990 have not linked technology-based standards in any direct way to the attainment of specified health goals. For the immediate future, at least, living with these amendments means making the most of MACT. □

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The Administrator shall, within 90 days after December 31, 1970, publish (and shall from time to time thereafter revise) a list which includes each hazardous air pollutant for which he intends to establish an emission standard under this section.
Within 180 days after the inclusion of any air pollutant in such list, the Administrator shall publish proposed regulations establishing emission standards for such pollutant together with a notice of a public hearing within thirty days. Not later than 180 days after such publication, the Administrator shall prescribe an emission standard for such pollutant, unless he finds, on the basic of information presented at such hearings, that such pollutant clearly is not a hazardous air pollutant. The Administrator shall establish any such standard at the level which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant.
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